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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,705	03/30/2004	J. Richard Gyory	ALZA-0377/ALZ5016USANP	7214
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EXAMINER GILBERT, ANDREW M				
ART UNIT		PAPER NUMBER		
3767				
NOTIFICATION DATE		DELIVERY MODE		
09/30/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@woodcock.com

Office Action Summary

Application No.

10/814,705

Applicant(s)

GYORY, J. RICHARD

Examiner

ANDREW M. GILBERT

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/06)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 6/16/2008.
2. In the reply, the applicant amended claims 17-19.
3. Thus, claims 17-21 are pending for examination.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 17-21 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Flower (5857994). Flower discloses an electrotransport device (Fig 1) comprising: a reservoir and a non-conductive housing (4) for the reservoir that comprising a substantially flexible electrically conductive element (8, 26) integrally molded within the non-conductive housing (Fig 1-2, wherein the housing 4 is shown by the dotted lines in Fig 2 and the conductive element is shown outside the housing 26 and entering the housing 4 to contact 8), wherein a first portion (portion of 26 that contacts 8 inside the housing 4 – whose boundaries are shown by dotted lines in Fig 2) of the conductive element is within the non-conductive housing and

a second portion (portion of 26 outside of the dotted lines of 4 and that goes and contacts 27 – Fig 1, 2) of the element is disposed on the outside of the non-conductive housing and extends therefrom, and wherein a substantially liquid and moisture-impermeable bond is created between the material forming the non-conductive housing and the conductive element (Fig 1-2; col 4, lns 18-24, 36-44; discussion below in Response to Arguments); wherein the non-conductive housing is a single integral component (4, Fig 1, 2); wherein the electrotransport device is manufactured without the fabrication of openings or other passages through the non-conductive housing (4, Fig 1, 2); wherein the conductive element comprises a substantially planar member (26, Fig 1); wherein the conductive element includes a base member having a conductive coating disposed thereon (26; Fig 1, col 4, lns 28-31).

6. Flowers does not explicitly disclose that the conductive elements (8, 26) and the non-conductive housing (4) form a substantially liquid and moisture-impermeable bond. However, it would be obvious to one of ordinary skill in the art at the time the invention was made to the seal between the conductive elements (8,26) and (4) inherently has substantially liquid and moisture-impermeable characteristics (see MPEP 2112). It is clear that the housing is substantially liquid and moisture impermeable because the housing contains liquid therapeutic agents, saline, or conductive gels (col 4, lns 18-24, 36-44). Additionally, it is clear that the electrical connectors (8, 26) are housed both inside the housing (8, 26) and external to the housing (26; discussion above). As shown in Figs 1-2, the electrical connectors (8 and 26) are clearly sealed into housing 4 and as electrical connectors (26) travel to tab (32) and connect with exposed connector

(34). Since the electrical connectors (8, 26) contact the non-conductives and the liquid therapeutic agents, saline, or conductive gels housed therein and additional travel outside the housing to tab (32) and exposed connector (34) and this occurs via a seal between the housing and the electrical connectors and result in no leaking or loss of non-conductive fluid, it is obvious and necessarily flows from Flowers that the seal/bond created between the material forming the non-conductive housing and the conductive element is substantially liquid and moisture-impermeable. Additionally, see response to arguments below.

7. Claims 17-21 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kuribayashi et al (6915159). Kuribayashi et al discloses an electrotransport device (Fig 1-12) comprising: a non-conductive non-conductive housing for the non-conductive of the electrotransport device comprising a substantially flexible electrically conductive element (2, 14, 15, Fig 1a-c, 5a-b, 6a-c) integrally molded within the non-conductive housing (1), wherein a first portion (2, 14, or 15, that contacts conductive drug layer 9, 12, or 13 – Fig 1a-c, 5a-b, 6a-c) of the conductive element is within the non-conductive housing and a second portion (2, 14, 15 that is exterior and forms exterior connector that can be connected to 18 – see Fig 5b, 6b-c, 8) of the element is disposed on the outside of the non-conductive housing and extends therefrom, and wherein a substantially liquid and moisture-impermeable bond is created between the material forming the non-conductive housing and the conductive element (Fig 1a-c, 5a-b, 6a-c, 8; col 3, lns 20-25, 53-55, 60-

Art Unit: 3767

col 4, lns 5, lns 12-14, 44-46; col 5, lns 59-64, col 6, lns 6-9, lns 28-39; col 7, lns 63-65; col 8, lns 13-16; col 19, lns 20-57; and col 21, lns 42-45; and discussion below); wherein the non-conductive housing is a single integral component (1; Figs 1, 5a-d, 6a-c, 8); wherein the electrotransport device is manufactured without the fabrication of openings or other passages through the non-conductive housing (Figs 1, 5a-d, 6a-c, 8); wherein the conductive element comprises a substantially planar member (2, 14, 15; Figs 1, 5a-d, 6a-c, 8); wherein the conductive element includes a base member having a conductive coating disposed thereon (col 7, lns 1-5, 39-47).

8. Kuribayashi et al does not explicitly disclose that the conductive elements (8, 26) and the non-conductive housing (4) form a substantially liquid and moisture-impermeable bond. However, it would be obvious to one of ordinary skill in the art at the time the invention was made to the seal between the conductive elements (8,26) and (4) inherently has substantially liquid and moisture-impermeable characteristics (see MPEP 2112). First, the teachings of Kuribayashi et al (Fig 1a-c, 5a-b, 6a-c, 8; col 3, lns 20-25, 53-55, 60-col 4, lns 5, lns 12-14, 44-46; col 5, lns 59-64, col 6, lns 6-9, lns 28-39; col 7, lns 63-65; col 8, lns 13-16; col 19, lns 20-57; and col 21, lns 42-45) clearly disclose a desire and capability for substantially liquid and moisture-impermeable seals between components to maintain proper drug stability and sealing of the conductive layers. Explicitly disclosed is the fact that the materials used in constructing the non-conductive housing are water-impermeable materials, water-proof, and oil proof. Additionally, explicitly disclosed it the fact that a water evaporation test that tested the devices ability to maintain liquid within the non-conductive housing without evaporation

loss resulted in nearly 100% retention. Finally, the conductive elements (2, 14, 15) are within the housing (1) in direct contact with the liquid non-conductives and are external to the housing (ie shown in 14, 15, Fig 6b) and are connected to external power via connector (18; Fig 8; additionally see above citations for discussion in specification). Since the electrical connectors (2, 14, 15) contact the non-conductives and the liquid non-conductives and additional travel outside the liquid impermeable housing (1) to be connected to power source (18) and this occurs via a seal between the housing and the electrical connectors and results in no leaking or loss of non-conductive fluid (see above citations), it is obvious and necessarily flows from Kuribayashi et al that the seal/bond created between the material forming the non-conductive housing and the conductive element is substantially liquid and moisture-impermeable. Additionally, see Response to Arguments below.

9. Claims 17-21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Phipps et al (4747819). Phipps et al discloses an electrotransport device (Fig 1) comprising: a reservoir (18) and a non-conductive housing (12) for the reservoir that comprises a substantially flexible electrically conductive element (20, 23) integrally molded within the non-conductive housing, wherein a first portion of the conductive element is within the reservoir non-conductive housing (23) and a second portion (20) of the element is disposed on the outside of the non-conductive housing and extends therefrom, wherein the non-conductive housing is a single integral component (Fig 1); wherein the electrotransport

device is manufactured without the fabrication of openings or other passages through the non-conductive housing (Fig 1; Summary); wherein the conductive element comprises a substantially planar member (23); wherein the conductive element includes a base member having a conductive coating disposed thereon (col 8; Ins 64-66).

10. However, Phipps et al does not explicitly disclose that the conductive elements (20, 23) and the non-conductive housing (12) form a substantially liquid and moisture-impermeable bond. However, it would be obvious to one of ordinary skill in the art at the time the invention was made that the seal between the conductive elements and the non-conductive housing inherently has substantially liquid and moisture-impermeable characteristics (see MPEP 2112) because the conductive element traverses the non-conductive housing wall and the fluid from the reservoir does not leak out of the housing.

Response to Arguments

11. Applicant's arguments filed 1/31/2008 have been fully considered but they are not persuasive.

12. The Applicant argues that Flower and Kuribayashi et al do not teach a first portion of the conductive element being within the non-conductive housing and a second portion being disposed on the outside of the non-conductive housing and extends therefrom and the electrode layer is not integrally molded within a non-conductive housing.

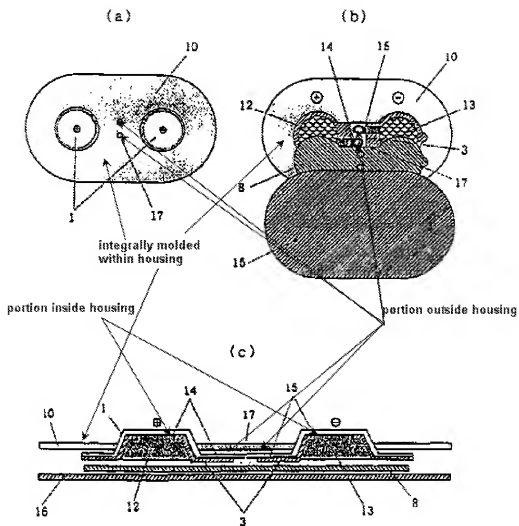
13. In response to the applicant's arguments against Flower, the Examiner notes that Figure 2 shows the electrical connectors (26) connected to the electrodes (8, 10)

running from inside the housing that is designated by the dotted line 4 to the external environment by crossing the dotted line 4 and connecting to the external controller (2). The dotted line annotation on the drawing is standard in the art to designate element boundary. In the instant case, the dotted line designates the boundary of the non-conductive housing. Thus, the device of Flower reads on the applicant's claimed invention.

14. Furthermore, the Examiner notes that the external connectors (34) are also electrically conductive and explicitly disclosed and shown in Flower as being exposed. The scope of the conductive element as recited in the claim is such that the combination of the electrical connector (26) (e.g. being a first portion of the conductive element) and the external connector (34) (e.g. being a second portion of the element disposed outside of the housing and extending therefrom) reads on the applicant's claim recitation. In this additional way, Flower discloses the applicant's claimed invention. The rejection is maintained.

15. In response to the applicant's arguments against Kuribayashi et al, the Examiner disagrees and notes that Kuribayashi clearly shows the conductive elements (2, 14, 15) having a first portion disposed within the housing in direct contact with the reservoir and are external to the housing and are connected to external power via connector (See Annotated Figure below and also Fig 8 which explicitly shows the external connection to conductive elements). The rejection is maintained.

Fig. 6



16. Lastly, the Examiner cites Phipps et al as an additional reference. The Examiner notes the applicant's claimed invention is still very broad.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **ANDREW M. GILBERT** whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/

Examiner, Art Unit 3767

/Kevin C. Simmons/

Supervisory Patent Examiner, Art Unit 3767